

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Study of safety and effectiveness of mesenchymal stem cells condition medium and 665nm low level diode laser hat in the treatment of androgenetic alopecia

Protocol summary

Study aim

Study of safety and effectiveness of mesenchymal stem cells secretome and 665nm low level diode laser hat in the treatment of androgenetic alopecia

Design

This study is performed in phase 1 and 2 on 30 patients with hair loss. In each session, the first group is treated with CM injection in five sessions with an interval of one month between each. The second group is treated with a laser cap three times a week for 10 minutes each time. The third group is treated with CM injections in five sessions with an interval of one month each, during which they use a laser helmet three times a week for 10 minutes.

Settings and conduct

This project is performed in the Skin and Stem Cell Research Center of Tehran University of Medical Sciences and patients are divided into three groups: treated with CM injection, laser cap, CM injection and laser cap.

Participants/Inclusion and exclusion criteria

Inclusion criteria: androgenetic alopecia type 2-4, no use of topical or oral medication for the treatment of alopecia during the last six months. Exclusion criteria: age under 18, pregnancy, lactation, history of malignancies, take any topical or systemic treatment during the study.

Intervention groups

The first group is treated with CM injection in five sessions with an interval of one month each. The second group is treated with a laser cap three times a week for 10 minutes each time. The third group is treated with CM injections in five sessions with an interval of one month each, during which they use a laser helmet three times a week for 10 minutes.

Main outcome variables

The amount of hair loss; side effects; patient's satisfaction; tolerability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200127046282N27**

Registration date: **2023-04-23, 1402/02/03**

Registration timing: **prospective**

Last update: **2023-04-23, 1402/02/03**

Update count: **0**

Registration date

2023-04-23, 1402/02/03

Registrant information

Name

Sona Zare

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2665 7438

Email address

sonazarebio@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-30, 1402/02/10

Expected recruitment end date

2023-08-01, 1402/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of safety and effectiveness of mesenchymal stem cells condition medium and 665nm low level diode laser hat in the treatment of androgenetic alopecia

Public title

Comparison of the efficacy of mesenchymal stem cells condition medium injection and ow level laser in the treatment of alopecia

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Androgenetic alopecia Type 2-4 Do not take topical or oral medication to treat alopecia in the last six months

Exclusion criteria:

Age under 18 years Pregnancy Breastfeeding History of malignant diseases Take any topical or systemic treatment during the study

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Patients are divided into three groups. The first group is treated with condition medium (CM) injection in five sessions with an interval of one month each. The second group is treated with a laser cap three times a week for 10 minutes each time. The third group is treated with CM injections in five sessions with an interval of one month each, during which they use a laser helmet three times a week for 10 minutes. The data analyzer was considered blind in this study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Organizational committee of ethics in biomedical research Shahid Beheshti University of Medical Scie

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi Ave, Yaman Ave, Velenjak

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2022-11-13, 1401/08/22

Ethics committee reference number

IR.SBMU.REC.401.020

Health conditions studied**1****Description of health condition studied**

Hair loss

ICD-10 code

L64.9

ICD-10 code description

Androgenic alopecia, unspecified

Primary outcomes**1****Description**

The amount of hair loss

Timepoint

Before treatment and one month after the last session

Method of measurement

Trichoscan

Secondary outcomes**1****Description**

side effects

Timepoint

One week after session

Method of measurement

Questionnaire and visit

2**Description**

satisfaction

Timepoint

One months after the last session

Method of measurement

Questionnaire and visit

3**Description**

Tolerability
Timepoint
Each session after transplantation
Method of measurement
Questionnaire and visit

Intervention groups

1

Description
Control group: Patients are treated with CM injections in five sessions with an interval of one month each.
Category
Treatment - Other

2

Description
Control group: Patients are treated with laser caps three times a week for 10 minutes each time.
Category
Treatment - Other

3

Description
Intervention group: Patients are treated with CM injections in five sessions with an interval of one month each, during which they wear a laser helmet three times a week for 10 minutes.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Skin and Stem cell Research Center of Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Nilforoushzadeh
Street address
No 4, Maryam Alley, South Kamraniyeh Street, Tehran, Iran
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1937957511
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Email
nilforoosh@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sadi Banar
Street address
Laser Application in Medical Sciences Research Center, Shohadaye-Tajrish Educational Hospital, Tajrish Sq, Tehran, Iran
City
Tehran
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Tehran
Postal code
1989934370
Phone
+98 21 2271 8021
Email
laser.cntr@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Skin and stem Cell Research Center, Tehran University of Medical Sciences
Full name of responsible person
Sona Zare
Position
Researcher
Latest degree
Ph.D.
Other areas of specialty/work
Cellular and Molecular Biology
Street address
No 4, Maryam Alley, South Kamraniyeh Street, Tehran
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Skin and Stem Cell Research Center, Tehran
University of Medical Sciences

Full name of responsible person

Mohammad Ali Nilforoushzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable